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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,361	02/13/2001	Yu-Wen Hu	4757US	1070

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EXAMINER
STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
1656	8

DATE MAILED: 11/16/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

substitute copy; both copies were mailed to applicant

Office Action Summary	Application No.	Applicant(s)	
	09/~~728,361~~ 782,361	~~BIBLE, ET AL.~~ HU	
	Examiner	Art Unit	
	Teresa E Strzelecka	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

1. A substitute specification excluding the claims is required pursuant to 37 CFR 1.125(a) because the changes requested in the preliminary amendment filed on February 13, 2001 are too numerous to be entered as an amendment.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

§ 1.125 Substitute specification.

(a) If the number or nature of the amendments or the legibility of the application papers renders it difficult to consider the application, or to arrange the papers for printing or copying, the Office may require the entire specification, including the claims, or any part thereof, be rewritten.

(b) A substitute specification, excluding the claims, may be filed at any point up to payment of the issue fee if it is accompanied by:

(1) A statement that the substitute specification includes no new matter; and

(2) A marked up version of the substitute specification showing all the changes (including the matter being added to and the matter being deleted from) to the specification of record. Numbering the paragraphs of the specification of record is not considered a change that must be shown pursuant to this paragraph.

(c) A substitute specification submitted under this section must be submitted in clean form without markings as to amended material. The paragraphs of any substitute specification, other than the claims, should be individually numbered in Arabic numerals so that any amendment to the specification may be made by replacement paragraph in accordance with § 1.121(b)(1).

(d) A substitute specification under this section is not permitted in a reissue application or in a reexamination proceeding.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Fahy (WO 96/30545).

Regarding claims 1, 2 and 8 Fahy teaches a method of simultaneous determination of related polynucleotide sequences, for example, within the same gene, in a nucleic acid sample by:

- providing a nucleic acid sample which contains at least two related polynucleotide sequences, each with an identical region and a divergent region,
- providing a primer complementary to the identical regions,
- extending the primer into the divergent regions in the presence of a polymerase and an incomplete set of dNTP's (at most three),
- separating the extension products based on their lengths (page 7, lines 18-37).

Primers may be labeled with fluorescent labels (page 8, lines 12-14). Samples may be obtained from patients' cells, such as blood cells (page 29, lines 17-21). The polymerase used in the method is a high-fidelity polymerase (with 3'-> 5' exonuclease activity), such as Pfu (page 20, lines 3-34). Characterization of the extension products is achieved by comparing lengths of the extension products using size separation methods, including gel electrophoresis, capillary electrophoresis or mass spectrometry (page 21, lines 3-14).

Regarding claim 3, a target nucleic acid from a sample may be amplified before the extension (page 17, lines 22-35).

Regarding claims 4 and 5, two or three dNTPs are used in primer extension (page 18, lines 26-30).

Regarding claim 6, labels may be fluorescent, luminescent or radioactive (page 15, lines 34-37; page 16, lines 1-3).

Regarding claim 7, dNTPs used for extension may be labeled (page 21, lines 27-31).

Regarding claims 9 and 10, extension products are analyzed on an automated sequencer with BioImage Analyzer software (page 34, lines 13-32).

4. Claims 1-7, 9-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Hu et al. (Nucl. Acids Res., vol. 26, pp. 5013-5015, November 1, 1998).

Regarding claims 1-12, Hu et al. teach primer specific and mispair extension analysis (PSMEA) method, in which Pfu DNA polymerase is used to extend a template with an incomplete set of dNTPs, allowing detection of nucleotide variations. PCR-amplified HCV samples were subject to primer extension reactions using ^{32}P-labeled dNTPs or primers, with two or three dNTPs in one reaction. Primer extension products were separated by gel electrophoresis

(Abstract, Fig. 1, Fig. 2). The results of primer extension were confirmed by direct sequencing (Fig. 3).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 11 and 12 (SEQ ID NO: 2, 6, 7) are rejected under 35 U.S.C. 103(a) as being unpatentable over Fahy as applied to claim 1 above, and further in view of Resnick et al. (U.S. Patent No. 5,527,669).

A) Claim 11 is drawn to an HCV genotype, and claim 12 to a primer selected from the group consisting of SEQ ID NO: 1-15.

B) Teachings of Fahy have been described above.

C) Resnick et al. teach oligonucleotide primers which can be used to amplify and detect HCV nucleic acids. Primers with SEQ ID NO: 8, 15 and 18 (overlapping with SEQ ID NO: 6, 7 and 2, respectively) can be used to amplify HCV genotypes from Japan , USA and HCV-C9 (col. 27, lines 57-66).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the HCV detection primers of Resnick et al. in the method of Fahy. The motivation to do so, expressly provided by Fahy, would have been that this method simultaneously detected related polynucleotides with different mutations, was performed in a single reaction and was amenable to automation.

7. Claims 11 and 12 (SEQ ID NO: 4) are rejected under 35 U.S.C. 103(a) as being unpatentable over Fahy as applied to claim 1 above, and further in view of Okamoto (U.S. Patent No. 5,550,016).

A) Claim 11 is drawn to an HCV genotype, and claim 12 to a primer selected from the group consisting of SEQ ID NO: 1-15.

B) Teachings of Fahy have been described above.

B) Okamoto teaches oligonucleotide primers which can be used to amplify and detect different HCV strains. Primer with SEQ ID NO: 18 (overlapping with SEQ ID NO: 4) can be used to detect HCV strains I-VI (col. 3, lines 34-39).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the HCV detection primer of Okamoto in the method of Fahy. The motivation to do so, expressly provided by Fahy, would have been that this method simultaneously detected related polynucleotides with different mutations, was performed in a single reaction and was amenable to automation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS
May 17, 2002